DIVISION OF GASTROINTESTINAL AND COAGULATION DRUG PRODUCTS

ADDENDUM TO MEDICAL OFFICER'S SAFETY UPDATE REVIEW FINALIZED 7/20/2001

NDA:	21-345 SU, BM
IND:	51,196/ N-163, 164, 165, 166
Sponsor:	Fonda BV
Drug Product:	Arixtra™ (fondaparinux sodium, ORG31540/SR90107A)
Date submitted:	June 15, 2001; July 3, 2001; June 6, 2001; June 15, 2001; June 18, 2001; June 22, 2001
Review completed:	July 17, 2003
Reviewer:	Kathy M. Robie-Suh, M.D., Ph.D.

Regarding the case of heparin-induced thrombocytopenia mentioned on page 11 of the above dated safety update review:

Review of additional information made available June 23, 2003 shows that the sentence included in this review indicating that a case of heparin induced thrombocytopenia (HIT) had been attributed to fondaparinux sodium by the investigator is incorrect. The patient actually received unfractionated heparin to which the investigator attributed the association, not fondaparinux sodium.

See also Medical Team Leader Memorandum to IND 51,196 dated June 27, 2003.

cc:
NDA 21-345
IND 51,196
IND 51,126
HFD-180/RJustice
HFD-180/JKorvick
HFD-180/KRobie-Suh
HFD-180/DMoore
HFD-180/JChoudary
HFD-180/LZhou
HFD-720/TPermutt
HFD- 180/SDoddapaneni

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/s/

Kathy Robie-Suh
7/17/03 01:54:41 PM
MEDICAL OFFICER